Blood Vessel Closure Clip and Delivery Device

This invention relates to a clip for closing a puncture hole in a blood vessel, and to a device for closing a puncture hole using such a clip.

Numerous medical diagnostic and interventional procedures involve the use of long catheters which are placed within the human vascular system. These catheters are delivered over guide wires to positions in the heart for cardiac procedures and into the brain for neurological procedures. The point of entry is normally a puncture hole in the femoral artery in the patient's groin. Once the procedure has been completed the catheter and guide wire are removed and the puncture hole must be closed in order to prevent excessive bleeding and the possibility of infection. Traditionally this puncture hole has been closed by maintaining manual pressure at the puncture site until homeostasis occurs around the puncture hole or placing sand bags on an area of the groin close to the puncture hole and keeping the patient immobilised until homeostasis occurs.

In recent times a number of medical devices have been developed and marketed for the purpose of closing this puncture hole. These devices fall broadly into two categories (a) mechanical closure devices such as those which use sutures or staples to mechanically close the puncture hole, and (b) occlusion devices such as collagen plugs and gels. Examples of prior art in this area include US Patents 5,860,991 and 6,322,580.

US Patent 5,860,991 describes a device for closing puncture holes utilizing a suture. The device is positioned into the artery over the guide wire until a blood signal appears at the proximal end indicating proper position has been attained. At this point an internal anchor is deployed and needles are advanced from outside the artery, through the arterial wall and into the anchor component to grab opposite ends of a suture loop. The needles are then retracted back into the device and the device is removed from the artery leaving the open ends of the suture external on the patients skin. A knot is tied and run down the suture tightening the loop around the puncture hole and closing it. A cutter device is then used to cut the suture.

The problems associated with this device are the significant number of steps in its use, tying of the suture loop involves a sawing action around the puncture hole which could unintentionally cause the suture to cut its way through the hole, pushing needles from outside the artery to inside creates two additional puncture holes and finally a loop of suture remains inside the artery and has the potential to dislodge plaque within the artery.

Another example of a mechanical closure device is described in US Patent 6,322,580 which uses a metallic staple to close the puncture hole. This device involves the use of a special dilator and sheath which are guided into the femoral artery over a guide wire. Once the guide wire is removed internal stabilizers are activated and retracted against the internal wall of the artery. The sheath dilator is then removed and a stapler device is advanced through the sheath and the staple deployed into the arterial wall. The stapler is then removed, the stabilisers deactivated and the introducer sheath removed from the tissue tract.

Problems associated with this device include the use of a specialised sheath which must be inserted over the guide wire and advanced into the tissue tract before the closure procedure can take place. In addition delicate stabiliser type devices must be deployed within the artery before the stapler can be delivered to close the puncture hole. Once the staple is delivered the staple device is removed from the sheath, the internal stabilisers are then collapsed and retracted through the puncture hole and into the sheath before the sheath itself can be removed from the tissue tract.

While both devices described above are effective in terms of closing puncture holes they are mechanically complex in nature in terms of operation. In addition a significant number of steps are involved in the procedure. The end users of such devices are more familiar with catheter-based technologies delivered over guide wires, combined with the inflation and deflation of balloons. Therefore there is a need for an improved puncture closure device which operates in a manner more consistent with catheter based devices such as angiography and angioplasty catheters. In addition there is a need to reduce the

complexity of such devices by reducing the number of components involved and the number of steps involved in the procedure.

Accordingly, the present invention provides a clip for closing a puncture hole in a blood vessel, the clip comprising a ring having a resiliently expandable circumference and a plurality of barbed prongs extending at least approximately in the same direction from one edge of the ring.

The ring may be circular or any suitable closed-loop shape.

The invention further provides a device for closing a puncture hole in a blood vessel using a clip of the kind aforesaid, the apparatus comprising an elongated body having a front end for insertion through the hole into the blood vessel and a clip expander positioned on the body rearwardly of the front end for receiving the clip with its ring surrounding the expander and its prongs projecting towards the front end of the body, the clip expander being actuable to resiliently expand the circumference of the ring, the clip being movable forwardly in its expanded state so that the prongs pierce the tissue around the hole, and the clip expander thereafter being actuable to release the clip so that the body and clip expander can be withdrawn from the ring.

In one embodiment the clip, herein referred to as a "ring occluder", is placed over a deflated balloon which in turn is bonded to the shaft of a plastics catheter. Inflation of the balloon exerts an outward expanding force under the ring occluder causing it to expand to a diameter equivalent to a fully expanded diameter of the balloon on which it sits. Barbed legs extend from one edge of the occluder ring for a distance of 3-5mm. The catheter has three lumen, one provides a channel for liquid to inflate the balloon, one is a channel for blood and the third channel accommodates the guide wire.

In clinical use the catheter is positioned on the guide wire and delivered over the guide wire through the tissue tract and into the blood vessel. The catheter is advanced until a blood signal appears at the blood back port. This indicates that the blood entry port is

now positioned within the blood vessel. The catheter is now retracted until blood flow stops indicating that the blood entry port is now positioned within the puncture hole and the ring occluder is positioned a pre-determined distance form the wall of the blood vessel. The guide wire may now be removed. The balloon is then inflated using saline solution which in turn causes the ring occluder to increase in diameter and expand outward into the tissue tract. The diameter of the balloon on the rear side of the ring occluder is greater in diameter so as to provide a shoulder or edge to advance the ring occluder forward. Once fully expanded the catheter is pushed forward causing the barbed legs of the ring occluder to penetrate the surrounding tissue and arterial wall in the proximity of the puncture hole. The catheter continues to advance until significant forward resistance is met. This indicates to the user that the catheter should not be advanced any further as the barbed legs should now be positioned within the arterial wall. The expanding balloon is then deflated, the guide wire removed from the catheter and the catheter removed from the tissue tract. On removal of the catheter the recoiling force of the ring occluder will pull the edges of the puncture hole together thereby sealing the hole closed.

In another embodiment the balloon is replaced by a sliding collar which has splines which are forced mutually outwards to deform the ring occluder.

The advantage of such devices are that they are significantly simpler to operate than previously described mechanical closure devices. In addition, the mode of operation of the balloon device is consistent with that of other devices used by interventional radiologists and cardiologists in that it provides a catheter delivered over a guide wire with a balloon which is inflated from an external port.

Embodiments on the invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Fig. 1 is a perspective view of one embodiment of a ring occluder according to the invention in both its unexpanded and expanded conditions.

Fig. 2 is a perspective view of a second embodiment of a ring occluder in its unexpanded and expanded conditions.

Fig. 3 is a plan view of a first embodiment of catheter delivery device for the ring occluder of Fig. 1 or Fig. 2.

Fig. 4 is an enlarged view of the delivery device of Fig. 3 in the region of the ring occluder and inflatable balloon.

Fig. 5 is a cross sectional view of the catheter on the plane A-A of Fig. 3.

Figs. 6-10 illustrate successive stages of the catheter delivery device in use.

Fig. 11 is a perspective view of a second embodiment of catheter delivery device in a non-expanded condition.

Fig. 11(A) is a cross sectional view of the second embodiment of catheter on the plane A-A of Fig. 12.

Fig. 12 is an elevational view of the device shown in Fig. 11.

Fig. 13(A) is an elevational view of the ring occluder deployment means (expander) of the second embodiment of catheter delivery device in its initial rest position.

Fig. 13(B). is an elevational view of the expander of Fig. 13(A) in its mid-forward and fully expanded state.

Fig. 13(C). is an elevational view of the expander of Fig. 13(A) in its fully forward and collapsed state.

Figs. 14 and 15 illustrate successive stages of the second embodiment of catheter delivery device in use.

Referring first to Fig. 1, a ring occluder 10 for closing a puncture hole in a blood vessel comprises a circumferentially continuous metal ring 12. The circumference of the ring 12 is sinuous and the ring has a plurality of sharp metal prongs 14 extending at least approximately in the same direction from one edge (in Fig. 1 the lower edge) of the ring 12. The prongs are 3-5mm in length and extend from alternate minima of the sinuous shape. The prongs 14 are barbed, meaning in the present context that they are configured to resist withdrawal once they penetrate tissue. The prongs 14 preferably mutually converge slightly towards the centre axis of the ring 12. Fig. 1(a) shows the ring occluder in its non-expanded state, while Fig. 1(b) shows the ring occluder in its expanded state where the pitch between the peaks of the sinuous configuration have been increased in a manner which provides uniform expansion of the ring at all points on its circumference. The pitch between the barbed prongs increases accordingly.

Fig. 2(a) shows an alternative embodiment of ring occluder 10' in its non-expanded state. In this case the circumference of the ring 12' is made up of a plurality of oval-shaped segments 16 each with a longitudinal central slit 18. The oval segments 16 are disposed side-by-side round the ring 12 with their longitudinal axes substantially parallel. Each oval segment 16 is joined to the next by a narrow central waist 20. On expansion of the ring as illustrated in Fig. 2(b) the oval segments expand to a more round or open configuration therefore increasing the overall diameter of the ring 12 and the pitch between the barbed legs 14 which extend from the base of every second oval segment.

In both cases the material used to fabricate the ring occluders 10 and 10' is such that permanent metal deformation does not occur on expansion of the occluder from its non-expanded state to its expanded state. The force exerted on the occluders is such that they remain within the elastic range of the material used thereby ensuring that when the expanding force is removed the occluder returns resiliently to its non-expanded state. Preferably the diameter of the ring 12 can be resiliently increased by a factor of three

with return substantially to its original diameter upon removal of the expanding force. An example of a suitable material for making the occluder is Nitinol or Memory Metal.

Figs. 3 to 5 show a first embodiment of catheter delivery device with a ring occluder 10 in position (the device could just as well be used with the ring occluder 10'). The catheter 22 is a flexible, elongated plastics body having a longitudinal bore 24 (Fig. 5) by which the catheter can be slid along a pre-positioned guide wire 26. The front end 28 of the catheter 22 is tapered down onto the guide wire 26 which guides it into position within the blood vessel 30, Fig. 6, through a hole 32 in the sidewall of the blood vessel. Between the front end 28 and the ring occluder 10 is a blood entry port 34. The port 34 allows blood to enter a further longitudinal bore 38 in the catheter 22. An inflatable enclosure ("balloon") 40 is positioned on the catheter 22 approximately 5cm to the rear of the extreme forward tip 28' of the front end 28. The balloon 40 coaxially surrounds the catheter and in its deflated state lies tightly against the catheter body. The ring occluder 10 is positioned on the balloon 40 toward its forward end, the ring 12 coaxially surrounding the balloon and catheter. A hub 42 is positioned at the rear end of the catheter 22 from which extends a blood port 44 connected to bore 38 within the catheter, which in turn is connected to blood entry port 34. In addition, there is a balloon inflation port 46 connected to a further longitudinal bore 48 in the catheter 22, the bore 48 communicating with the interior of the balloon 40. The port 46 allows fluid under pressure (such as a saline solution) to be delivered into the balloon 40 to inflate it, and also allows fluid in the balloon to be vented to allow it to revert to its deflated state.

Fig. 4 is a view of the device in the region of the ring occluder 10. The balloon 40 is formed with two axially adjacent regions 40a, 40b such that when the balloon is inflated these regions have different diameters, Fig. 7. In particular, when the balloon is inflated the front region 40a, around which the occluder 10 is positioned, has a lesser diameter than the adjacent rear region 40b. The reason for this is to provide a shoulder 40c behind the ring 12 with which the ring occluder 10 can be pushed forward into the tissue surrounding the puncture hole 32 by pushing the catheter 22 as a whole in a forward direction. Only the ring 22 is positioned on the balloon 40. The barbed prongs 14 extend

freely in a forward direction and converge slightly towards the catheter body. In order to ensure that, when the balloon is inflated, the region 40b does not expand at the expense of the region 40a, the region 40b and shoulder 40c are made of a thicker material than the region 40a.

Figs. 6 to 10 illustrate the device in clinical use. Referring first to Fig. 6, the catheter 22 is positioned on the guide wire 26 and slid forwardly thereon through the tissue tract until the front end 28 of the catheter enters the blood vessel 30. The catheter 22 is advanced forward until the blood entry port 34 enters the blood vessel indicated by blood flowing from the blood back port 44. Advancement of the catheter is stopped and the balloon 40 is then inflated, as illustrated in Fig. 7, by fluid pressure applied at the port 46. Inflation of the balloon causes the ring occluder 10 to resiliently expand. Once fully expanded the catheter 22 is advanced forwardly as shown in Fig. 8. In doing so the shoulder 40c on the balloon 40 pushes against the ring occluder 10 causing the prongs 14 to penetrating overlying tissue and the arterial wall. The catheter 22 is advanced until significant resistance prevents any further advancement. This indicates proper position of the ring occluder 10. Now the balloon 40 is fully deflated by venting through the port 46 resulting in some resilient contraction of the ring occluder 10 around the catheter 22 as illustrated in Fig. 9. Once fully deflated the guide wire 26 and catheter 22 are removed from the tissue tract and the puncture hole 32 causing the ring occluder 10 to resiliently contract to its initial state thereby pulling the edges of the puncture hole 32 together and effecting homeostasis. The closed ring occluder 10 remains positioned around the puncture hole on the artery as illustrated in Fig. 10.

Although the foregoing has shown the ring 12 or 12' as circular, and the balloon 40 circularly symmetric around the catheter 22, the ring does not need to be circular but can be any closed-loop shape as dictated by the cross-section of the balloon which can also vary. The term "ring" is to be interpreted accordingly.

Figures 11 to 13 show an alternative embodiment of a catheter delivery device for the ring occluder 10 or 10'. In place of the balloon 40 used in the previous embodiment, a

mechanical expander is used; otherwise, all features of the previous embodiment may be present in the current embodiment. The mechanical expander comprises an oversleeve 50 on the catheter 22. Fig 11(A) shows a cross-section through the catheter in the region of the oversleeve 50. The catheter has a longitudinal guide wire bore 24 and blood return bore 38 as previously described, and the sleeve 50 is seen coaxially surrounding the catheter body. The forward end 52 of the sleeve is fixed to the outer surface of the catheter, while the rear end 53 of the sleeve 50 is slidable on the catheter 22.. A section of the sleeve 50 intermediate its ends, onto which the occluder is mounted in use, is slit longitudinally to form a series of spines 54. Each spline 54 has four hinge points 54a, 54b, 54c and 54d, the hinge points 54a and 54d being at the front and rear ends of the spline and the hinge points 54b and 54c being intermediate them. The two intermediate hinge points 54b, 54c generally align with the upper and lower edges respectively of the expandable ring 12 section of the occluder 10 as illustrated in Fig 12.

In the unexpanded state as shown in Fig 13(a) the splines 54 lie flush with the catheter. If the rear end 53 of the sleeve 50 is slid along the catheter 22 towards the fixed front end 52 the splines 54 are forced mutually radially outwardly as shown in Fig. 13(b) thus resiliently expanding the occluder 10 and at the same time advancing it in a forward direction. With continued advancement of the rear end 53 of the sleeve the splines collapse mutually inwardly down onto the catheter thus releasing the occluder 10 from the splined section.

In clinical use the catheter 22 is slid over a guide wire 26 as shown in Fig. 14 until a blood signal is received at the port 44 thus indicating proper positioning. At this point the rear end 53 of the sleeve 50 is advanced causing the occluder 10 to resiliently expand and simultaneously advance to stab the wall 30 of the artery, Fig. 15(a). As the rear end 53 of the sleeve is advanced further it releases the occluder 10, Fig. 15(b), so that the catheter and guide wire can be retracted from the puncture hole 32 allowing the occluder 10 to fully contract and close the puncture hole, Fig. 15(c).

The invention is not limited to the embodiments described herein which may be modified or varied without departing from the scope of the invention.